

Application No.: 09/954,571

2 Docket No.: 220002066000 / UC 94-161-9

**REMARKS**

This paper is in response to the Office COMMUNICATION mailed September 07, 2004, and in further response to the Election/Restriction Requirement mailed August 13, 2003.

As noted in the instant Office COMMUNICATION, Applicants inadvertently failed to elect a species for claim 7. In the restriction requirement mailed August 13, 2003, the Patent Office alleged that claim 7 is generic to a plurality of disclosed patentably distinct species of treatment methods requiring different vascular permeabilizing agents: histamine, substance P, serotonin.

In response to the claim 7 species requirement, Applicants elect histamine, with traverse.

**Reasons to reconsider and withdraw restriction requirement**

Applicants respectfully request the Patent Office to reconsider and to withdraw the restriction requirement for the following reasons.

In Applicants' response mailed June 21, 2004, they respectfully requested the Patent Office withdraw the restriction requirement and rejoin Groups I, II and III. Applicants also respectfully requested the Patent Office to withdraw the "patentably distinct species" requirement as set forth on pages 4 to 7, of the Restriction Requirement mailed August 13, 2003. Applicants also respectfully requested the Patent Office withdraw, in part, the "patentably distinct species" requirement regarding "treatment methods requiring different steps for increasing dwell time of a fluid" as set forth on page 8, of the Restriction Requirement.

The instant invention is directed to novel methods for introducing nucleic acids into heart cells (cardiac myocytes). The methods of the invention are not limited to the introduction of any particular nucleic acid or gene, or, any particular vascular permeabilizing agents, e.g., histamine, substance P, or serotonin. For example, the nucleic acids that are incorporated into viral vectors and introduced into heart cells using the methods of the invention can include nucleic acids (e.g., genes or cDNAs) encoding a protein (which can be any endogenous or heterologous protein,

sd-223411

Application No.: 09/954,571

3 Docket No.: 220002066000 / UC 94-161-9

including structural proteins, "functional" proteins, "mutated" genes, and the like), an antisense RNA- or DNA- encoding gene or a nucleic acid encoding an siRNA, to name only a few examples. Additionally, any vascular permeabilizing agent can be used, e.g., histamine, substance P, or serotonin, to name only a few examples.

The specification provides elegant examples as proof of principle that the novel methods of the invention are effective for the introduction of nucleic acids into heart cells. These examples include, inter alia, introduction of various "mutant" forms of nucleic acids encoding phospholamban (PLB), for example, dominant negative forms of PLB, including the allegedly "patentably distinct" species groups set forth on pages 5 to 9 of the Restriction Requirement. However, Applicants respectfully aver that the novelty of the methods of the invention is independent of which nucleic acid is selected to be introduced into a heart cell by a method of the invention, or, what vascular permeabilizing agent is used. Thus, it is improper to define as separate "patentably distinct" inventions methods that use different nucleic acids or genes. It is improper to define methods that use the different exemplary nucleic acids described in the specification as separate "patentably distinct" inventions. Likewise, is improper to define methods that use different vascular permeabilizing agents, e.g., the exemplary vascular permeabilizing agents described in the specification as separate "patentably distinct" inventions.

Additionally, Applicants respectfully aver that after a complete search directed to the novel methods of the invention (which are not limited to use of any particular nucleic acid or gene or vascular permeabilizing agent) it would not be an undue burden for the Patent Office to also do a complete search regarding making and using the methods of the invention with any particular nucleic acid or gene or vascular permeabilizing agent. Similarly, after a complete search directed to novel methods of the invention using any particular nucleic acid or gene or vascular permeabilizing agent (e.g., the elected histamine), it would not be an undue burden for the Patent Office to also do a complete search regarding making and using the novel methods of the invention not limited to use of any particular nucleic acid or gene or vascular permeabilizing agent.

sd-223411

Application No.: 09/954,571

4 Docket No.: 220002066000 / UC 94-161-9

Accordingly, Applicants respectfully request rejoining of Groups I, II and III and withdrawing of the "patentably distinct species requirements" as set forth on pages 5 to 9 of the office action.

Applicants believe that no additional fees are necessitated by the present response and amendment. However, in the event any such fees are due, the Commissioner is hereby authorized to charge any such fees to Deposit Account No. 03-1952 referencing docket no. 220002066000. Please credit any overpayment to this account.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at (858) 720-5133.

Dated: October 5, 2004

Respectfully submitted,

By   
Gregory P. Einhorn

Registration No.: 38,440  
MORRISON & FOERSTER LLP  
3811 Valley Centre Drive, Suite 500  
San Diego, California 92130  
(858) 720-5133

sd-223411